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EXAMINER	
HEARD, THOMAS SWEENEY	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,271	GHOSAL, SHIBNATH	
	Examiner	Art Unit	
	Thomas S. Heard	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *20-25 and 30-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/15/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-19 and 26-29, in the reply filed on July 27, 2005 is acknowledged. The traversal is on the ground(s) that the search for Group I would uncover the methods of Groups II-IV. This is not found persuasive because the inventions above are patentably distinct. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. For example, the a search for a composition comprising Shilajit would not necessarily lead to a method of treating chronic stress disorder and vice versa, and would be burdensome. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicated above is deemed proper and is made FINAL

Claims method of making, Claims 20-25, and the methods of using, Claims 30-38, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 and 26-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As demonstrated by Shibnath Ghosal, Indian J. Indg. Medicine (1992), 9 pages 1 and 2, the composition as claimed is nothing more than Shilajit itself, which is known in the art as a "humic substance admixed with plant, animal, and microbial substances," see page 1 and 2. Shilajit is comprised of dibenzo-alpha-pyrones and lipids phosphocreatin. Further, being comprised of antimicrobial and animal remnants, phosphocreatin and chromo-proteins (proteins of color) would be inherently present in the concoction. Therefore, the claims are drawn to a natural product.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:
"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to shilajit extract containing oxygenated dibenzo-alpha-pyrone chromoproteins compounds.

(1) Level of skill and knowledge in the art:

The level of skill to practice the art of the instantly claimed invention is high with regard to isolation, fractionation, and characterization, particularly with respect to mass spectroscopy, nuclear magnetic spectroscopy, and other spectroscopic methods of determining the structure of a complex molecule.

(2) Partial structure: (3) Physical and/or chemical properties:

Dibenzo-alpha-pyrones conjugated covalently to other alleged elements, such as lipids, amino acids (peptide), chromo-peptides, phosphocreatin, caretenoids, and various metals.

(4) Functional characteristics:

Thought to have medicinal value from traditional systems, see Ghosal, S, "Shiljit: Its Origin and Vital Significance", Traditional Medicine, Proceedings of an International Seminar, Nov. 7-9, 1992, Hotel Taj Bengal, Calcutta, India-, pp. 308-319.

(5) Method of making the claimed invention:

Hot aqueous extracts assisted with organic solvent.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim 1-12 and 26-29 are a broad generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any structure class comprising dibenzo-alpha-pyrone. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. "MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the

specification. There is not a specific example of a compound comprising a dibenzo-alpha-pyrone that discloses specific chromo-proteins, lipids, and the various functional groups claimed for the dibenzo-alpha-pyrone moiety. The presumed structure example does not share a common core structure, as creatine (and the other functional moieties) can be presumably connected to R^3 or R^8 without any evidence. While having written description for dibenzo-alpha-pyrone identified in the specification tables and/or examples, the specification is void of specific peptides, organic molecules (lipids and chromo-peptides) that qualify for the functional characteristics claimed as the biomolecules. The claimed and disclose molecular structure is merely a potential structure based on chemical and not structural determination. Lipase reactions "suggested" that lower MW lipids were present and that higher MW proteins, "like B-48" might be present in dibenzo-alpha-pyrone, see pages 23 and 24 of the specification. The "suggestion" that "dibenzo-alpha-pyrone are associated with low/medium weight lipoproteins is also indicative of the molecule not being completely described as to have proper written description. Thus, there is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate

written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 1-19 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition of a fractionated extract of Shilajit, does not reasonably provide enablement for the specific compositions instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the relative skill of those in the art; (5) the predictability or unpredictability of the art; (6) the amount of direction or guidance

presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to specific compounds deduced from chemical analysis of a mixture of compound isolated from Shilajit. Thus, the claims taken together with the specification imply a specific chemical structure from a complex mixture that are purported to have pharmaceutical and nutritional properties.

(3) The state of the prior art:

Shilajit and Shilajit extracts are well known in the art and are well known to contain dibenzo-alpha-pyrone, see Ghosal, S, "Shiljit: Its Origin and Vital Significance", Traditional Medicine, Proceedings of an International Seminar, Nov. 7-9, 1992, Hotel Taj Bengal, Calcutta, India-, pp. 308-319.

(4) The relative skill of those in the art:

The relative skill of those in the art is high.

(5) The predictability or unpredictability of the art: *(6) The amount of direction or guidance presented and (7) The presence or absence of working examples: (8) The quantity of experimentation necessary:*

Since the defined core structure that is correlated with the pharmaceutical function remains largely unsolved, means for determining both is highly unpredictable.

The specification has provided an alleged structure, or best guess, of a generic. However, the specification does not provide *specific* examples of the claimed compounds.

Considering the state of the art as discussed by the Wands Factor above and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to synthesize and/or extract and test the compounds that might correlated to a generic structure and test them in a trail and error basis to determine which ones were active and what the structure is that is correlated to function. *It is the examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-19 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowland US Patent 5,405,613. Rowland discloses compositions of Shilajit or Shilajit extracts in combination with vitamins (Ca, Fe, K, Mg, Zn, Se in the ranges of 1- 500 ppm as 1 mg/L is approximately 1 ppm) as a pharmaceutical or nutritional supplement. Given the use of Shilajit directly, and not the extract, the composition as a

pharmaceutical and/or nutritional supplement would contain all of the alleged compounds instantly claimed in natural product claims 1-12 and 26-29. Therefore the composition as claimed is anticipated by '613.

Conclusion

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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